

Notice of Allowability

Application No.

09/741,106

Examiner

Chih-Min Kam

Applicant(s)

INNIS ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/5/04.
2. ☒ The allowed claim(s) is/are 1-11, 13-27, 73 and 88-98.
3. ☒ The drawings filed on 05 May 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 0304.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lisa Hemmendinger on March 25, 2004.

Examiner's Amendments to the Claims:

Claims 5-11 and 15-25 have been amended as follows:

5. (Currently amended) The chimeric protein of claim 2, wherein at least one of said flanking peptides comprises an amino acid sequence [capable of binding] that binds one or more cell surface components.

6. (Currently amended) The chimeric protein of claim 5, wherein said amino acid sequence [capable of binding] that binds one or more cell surface components is an amino acid sequence [capable of binding] that binds a glycosaminoglycan.

7. (Currently amended) The chimeric protein of claim 6, wherein said amino acid sequence [capable of binding] that binds a glycosaminoglycan is an amino acid sequence [capable of binding] that binds heparin.

8. (Currently amended) The chimeric protein of claim 7, wherein said amino acid sequence [capable of binding] that binds heparin is a heparin-binding domain from a protein, said protein selected from the group consisting of:

- (a) protease nexin-1;
- (b) protease nexin-2;
- (c) antithrombin III;
- (d) heparin cofactor II;
- (e) protein C inhibitor;
- (f) platelet factor 4;
- (g) bovine pancreatic trypsin inhibitor; and
- (h) ghilanten-related inhibitors.

9. (Currently amended) The chimeric protein of claim 7, wherein said amino acid sequence [capable of binding] that binds heparin is a heparin-binding domain selected from the group consisting of:

- (a) SEQ ID NO: 10;
- (b) SEQ ID NO: 11;
- (c) SEQ ID NO: 12;
- (d) SEQ ID NO: 13;
- (e) SEQ ID NO: 14;
- (f) SEQ ID NO: 15;
- (g) SEQ ID NO: 16;
- (h) SEQ ID NO: 17; and
- (i) SEQ ID NO: 18.

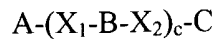
10. (Currently amended) The chimeric protein of claim 5, wherein said flanking peptide comprises the C-terminal of TFPI [[SEQ ID NO: 7]] (SEQ ID NO: 7).

11. (Currently amended) The chimeric protein of claim 5, wherein said flanking peptide comprises the C-terminal of TFPI-2 [[SEQ ID NO: 8]] (SEQ ID NO: 8).

15. (Currently amended) [The] A chimeric protein [of claim 14], wherein the chimeric protein comprises first and second amino acid sequences, said first amino acid sequence comprising SEQ ID NO: 19 and said second amino acid sequence selected from the group consisting of:

- (a) SEQ ID NO: 7;
- (b) SEQ ID NO: 8;
- (c) SEQ ID NO: 10;
- (d) SEQ ID NO: 11;
- (e) SEQ ID NO: 12;
- (f) SEQ ID NO: 13;
- (g) SEQ ID NO: 14;
- (h) SEQ ID NO: 15;
- (i) SEQ ID NO: 16;
- (j) SEQ ID NO: 17; and
- (k) SEQ ID NO: 18.

16. (Currently amended) The chimeric protein of claim 1, wherein said chimeric protein is represented by the generic structure:



wherein A and C are independently optional flanking peptides, the flanking peptides containing 1-100 amino acids;

wherein B is optional spacer peptides, the spacer peptide containing 1-25 amino acids;

wherein each X_1 is -D- K_1 -E-

where D, E are independently peptides of 1-25 amino acids,

where K_1 is (a) the Kunitz-type domain 1 of TFPI-2 or the mutein thereof or (b) the [TFPI] Kunitz-type domain 1 of TFPI or the mutein thereof;

wherein each X_2 is -F- K_2 -G-

where F, G are independently peptides of 1-25 amino acids,

where K_2 is (a) the Kunitz-type domain 2 of TFPI or the mutein thereof or (b) the Kunitz-type domain 2 of TFPI-2 or the mutein thereof[,]; and

wherein c is an integer from 1-10.

17. (Currently amended) The chimeric protein of claim 16, wherein A or C comprises Kunitz-type domain 3 of TFPI [[SEQ ID NO: 7]] (SEQ ID NO: 5).

18. (Currently amended) The chimeric protein of claim 16, wherein A or C comprises Kunitz-type domain 3 of TFPI-2 [[SEQ ID NO: 8]] (SEQ ID NO: 6).

19. (Currently amended) The chimeric protein of claim 16, wherein at least one of said flanking peptides comprises an amino acid sequence [capable of binding] that binds one or more cell surface components.

20. (Currently amended) The chimeric protein of claim 19, wherein said amino acid sequence [capable of binding] that binds one or more cell surface components is an amino acid sequence that binds a glycosaminoglycan.

21. (Currently amended) The chimeric protein of claim 20, wherein said amino acid sequence [capable of binding] that binds a glycosaminoglycan is an amino acid sequence [capable of binding] that binds heparin.

22. (Currently amended) The chimeric protein of claim 21, wherein said amino acid sequence [capable of binding] that binds heparin is a heparin-binding domain from a protein, said protein selected from the group consisting of:

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- (a) protease nexin-1;
- (b) protease nexin-2;
- (c) antithrombin III;
- (d) heparin cofactor II;
- (e) protein C inhibitor;
- (f) platelet factor 4;
- (g) bovine pancreatic trypsin inhibitor; and
- (h) ghilanten-related inhibitors.

23. (Currently amended) The chimeric protein of claim 21, wherein said amino acid sequence [capable of binding] that binds heparin is a heparin-binding domain selected from the group consisting of:

- (a) SEQ ID NO: 10;
- (b) SEQ ID NO: 11;
- (c) SEQ ID NO: 12;
- (d) SEQ ID NO: 13;
- (e) SEQ ID NO: 14;
- (f) SEQ ID NO: 15;
- (g) SEQ ID NO: 16;
- (h) SEQ ID NO: 17; and
- (i) SEQ ID NO: 18.

24. (Currently amended) The chimeric protein of claim 19, wherein said flanking peptide comprises the C-terminal of TFPI [[SEQ ID NO: 7]] (SEQ ID NO: 7).

25. (Currently amended) The chimeric protein of claim 19, wherein said flanking peptide comprises the C-terminal of TFPI-2 [[SEQ ID NO: 8]] (SEQ ID NO: 8).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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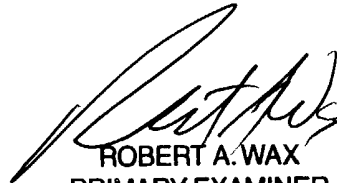
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

March 25, 2004


ROBERT A. WAX
PRIMARY EXAMINER